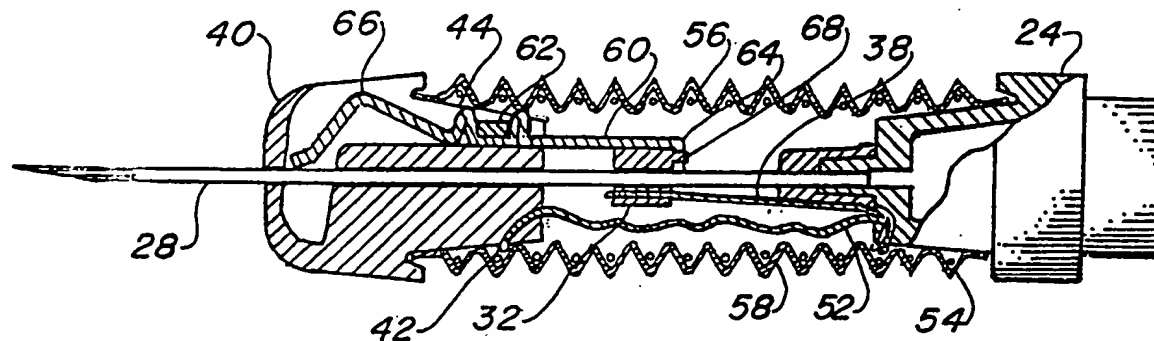




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification 5 : AGIM 5/32, 5/00</p>	<p>A1</p>	<p>(11) International Publication Number: WO 94/00172 (43) International Publication Date: 6 January 1994 (06.01.94)</p>
<p>(21) International Application Number: PCT/US92/05280 (22) International Filing Date: 22 June 1992 (22.06.92) (71)(72) Applicant and Inventor: WONG, Henry, C., C. [US/ US: 2509 Westminister Avenue, Alhambra, CA 91803 (US). (74) Agents: CISLO, Donald, M. et al.; Cislo & Thomas, 233 Ventura Boulevard, Suite 900, Santa Monica, CA 90401 (US). (81) Designated States: AT, AU, BB, BG, BR, CA, CH, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MW, NL, NO, PL, RO, RU, SD, SE, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE).</p>		<p>Published With international search report. With amended claims.</p>

(54) Title: AUTOMATIC DISPOSABLE NEEDLE GUARD



(57) Abstract

An automatic disposable needle guard for a hypodermic syringe and needle which has a sleeve (32) which slides over the needle and is limited in the travel in one direction by a sleeve lanyard (38). A guard (40) is positioned slidably upon the needle with a guard lanyard (52) limiting its travel from the syringe. An expanding flexible shield (54) is placed between the guard and the syringe exerting an expansive force against the lanyard (52). Clipped to the guard is a spring (60). When the guard is manually pulled toward the syringe or the needle penetrates a patient's tissue beyond the exposed length of the needle, the spring (60) trips permitting the shield to expand and cover the entire needle after use. Prior to maximum expansion, the spring having a protecting end (66), releases tension on the side of the needle and slips over the sharp end protecting and retaining the needle within the guard and shield for safe disposal.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FI	Finland				

AUTOMATIC DISPOSABLE NEEDLE GUARDTECHNICAL FIELD

5 This invention relates generally to hypodermic needles as used with a syringe and particularly to hypodermic needle guards that enclose the needle after use eliminating possible contact with the sharp injection needle which poses a serious health threat to medical, dental and clinical laboratory practitioners.

BACKGROUND ART

10 Various types of hypodermic needles currently exist in the art, with the object being to provide a protective cover or cap over the possibly wound-inflicting needle. Needles found in hypodermic syringes must be very sharp to quickly and easily
15 puncture the skin of the patient in order to provide medicinals beneath the layer of skin or remove blood for testing. Additionally, the hypodermic needle is usually very thin and long and hard to see, especially in low-light conditions. It is possible for medical
20 practitioners to accidentally prick themselves with the needle, either prior to or after a patient injection.

Pricking oneself prior to the injection of a solution does not present much of a health risk, since the needles to be used are sterilized. Also,
25 hypodermic syringes usually come with a needle cap which is secured over the top of the needle to prevent the accidental puncturing of the skin. When the health care worker takes off the needle cap, exposing the

needle, there is little risk of being injured by the
needle. However, upon placing the needle cap back onto
the needle, the fingers can be pricked by a slight
visual miscalculation or by a motorneuro mistake. The
5 consequences of this type of accident are more extreme.

Since the needle has already punctured the skin of
the patient, blood and body fluid possibly containing
viruses or infectious microorganisms, which may be
found in the patient, could be transferred to the
10 health care provider by a single accidental needle
prick.

Various types of diseases previously known could
be conveyed by such an accident, including Hepatitis B,
Hepatitis Non A, Non B and cytomegalovirus.

15 In the last decade, an even more menacing and
lethal virus, the Acquired Immune Deficiency Syndrome,
or AIDS virus, is easily communicated by such an
accidental and ultimately catastrophic event. Since
there is no known cure for AIDS at this time, a great
20 deal of care is required to prevent the accidental
prick of a hypodermic needle which has previously been
used on a patient.

Many types of syringes of one type or another have
been developed in an effort to address this problem yet
25 allow the ease of use of more conventional hypodermic
needles.

A search of the prior art did not disclose any
patents that read directly on the claims of the instant
invention however, the following U.S. patents were
30 considered related:

<u>PATENT NO.</u>	<u>INVENTOR</u>	<u>ISSUED</u>
5,104,384	Parry	14 Apr 1992
5,026,356	Smith	25 June 1991
5,015,242	Heifetz	14 May 1991
35 5,015,241	Feimer	14 May 1991
5,015,240	Soproni et al	14 May 1991

	5,013,305	Opie et al	7 May 1991
	4,973,344	Dombrowski	18 Dec 1990
	4,929,241	Kulli	29 May 1990
	4,926,416	Tomkiel	22 May 1990
5	4,921,490	Spier et al	2 May 1990
	4,725,267	Vaillancourt	16 Feb 1988
	4,664,654	Strauss	12 May 1987
	3,134,380	Armao	26 May 1964

10 Parry in U.S. patent 5,104,384 teaches a protective device that is spring loaded in its extended position. The user manually rotates the protective sleeve allowing the needle to be exposed and upon insertion into the tissue of a patient, the sleeve is further retracted unlatching the inner sleeve in a track. The outer sleeve extends over the needle by the urging of a compression spring when the needle is removed.

20 Patent number 5,026,346 issued to Smith discloses a safety device external to a syringe that has an L-shaped member that is manually slid forward covering the end of the needle after use.

25 A medical needle unit is presented in patent 5,015,242 of Heifetz where an elastic hood shaped protective element, in accordion shape, is compressibly restrained by a retaining element. When the needle is inserted into the patient, the retaining element is manually moved to the side permitting the elastic element to extend under its own memory contiguous with the patient's skin. When the needle is removed, the elastic element extends completely covering the needle.

30 Feimer in U.S. patent number 5,015,241 teaches a guide secured to a hypodermic syringe with a needle securing plunger fitted into the guide. The plunger has a groove at the end and a pocket to cover the needle tip. In use, when the injection is completed and the needle withdrawn from the patient, the plunger

is manually slid over the end of the needle and by the resilience of the bow shape of the plunger, the tip is not only protected as it slips over the end but prevents liquid from leaking from the needle.

5 Patent 5,015,240 issued to Soproni et al employ a bellows like retractable safety sheath of resilient material that covers the needle of a hypodermic syringe. The sheath is manually pulled back away from the needle when in use and springs back over the needle
10 when the injection is completed.

Opie et al disclose a sleeve with a cord and blocking member that slides over a hypodermic needle in patent 5,013,305. When an injection is completed, the medical practitioner slides the sleeve forward on the
15 needle pulling the blocking member into place over the center of the sleeve by the cord. The sharp end of the needle is enclosed by the sleeve and blocking member.

Patent number 4,929,241 issued to Kulli teaches a protective guard that is slid down to the distal end of the needle where it collapses inwardly in front of the
20 tip. The guard includes sharp blades that engage the needle preventing the guard from slipping once the device is activated. An optional spring loaded trigger mechanism deploys the guard when manually depressed.

25 Tomkiel discloses in Patent number 4,927,416 teaches a holder for use with a hypodermic syringe having a tubular protective sheath covering the needle and held extended with a spring.

A helical spring, covering the needle of a
30 syringe, is taught by Spier et al in patent 4,921,490. A hub and socket at the front end of the syringe support the spring. The convolutions in the distal end are tightly wound forming a cone for protection of the sharp end of the needle.

Patent number 4,725,267 issued to Vaillancourt discloses a sheath with and without spring actuation. The sheath covers the needle but is compressed to charge the syringe prior to injecting the patient. Before use the needle is covered with a shield or cap. After withdrawal of the needle from the patient, the sheath with a cap is moved forward to enclose the used needle.

For background purposes and as indicative of the art to which the invention relates reference may be made to the patents issued to Dombrowski, Strauss and Armao.

DISCLOSURE OF THE INVENTION

Currently, health care workers who use hypodermic needles of one type or another on a daily basis are not protected from accidental needlesticks. Accidental needle sticks often occur when an operator attempts to recap a needle after use or leaves a contaminated needle exposed on work surfaces where the operator or other workers accidentally impale themselves. Accidental needle stick injuries are extremely common in health care workers, such as physicians, dentists, nurses, laboratory workers and housekeeping personnel. Needle stick exposures can result in the transmission of Hepatitis B, AIDS and other transmissible diseases.

Newly introduced safety products such as needle recapping devices and manual safety locking syringes remain requiring the utmost precaution and attention from the health care workers. The required manual manipulation of these devices may still subject the health care workers to accidental needlesticks and potentially the deadly HIV virus infection due to a

fraction of a second of carelessness.

It is also desirable that after injection or blood sampling using a hypodermic needle, that the needle is safely and easily discarded without representing a continued health risk to anyone who may encounter the used hypodermic needle, either on the premises of the health care facility, or in transit or arrival at the refuse collection area or rubbish dump.

There is potentially a great need in the health care industry to have a hypodermic syringe and a vacuum tube syringe that provides the type of safety as discussed above. Further, the device should be readily operated, completely reliable, may be simply and inexpensively manufactured. Further, the device should have a great deal of versatility for different applications using various needles both in diameter and length, also different sized vacuum tubes and syringes.

The desirable features described above for hypodermic syringes and vacuum tube syringes are all provided for by the present invention.

The automatic disposable needle guard includes a disposable hypodermic needle which is equipped with a spring loaded, retractable guard. The device may have various length of needle shaft exposed initially for different applications, e.g., subcutaneous injection and blood collection. As the needle is inserted deeper beneath the skin, the anterior part of the apparatus contacts against the tissue and is compressed further as the needle is inserted deeper into the tissue. When the injection or blood collection is completed, the health care worker simply withdraws the needle and immediately after the needle leaves the skin, the automatic disposable needle guard expands forward beyond the needle point. Once the automatic disposable needle guard encloses the entire length of the needle, the needle point is guarded against any accidental

needle injuries. Even if the user accidentally hits the end of the syringe containing traces of contaminated blood, the needle is unable to penetrate through the guard affording complete safety for the medical practitioner.

These and other objects and advantages of the present invention will become apparent from the subsequent detailed description of the preferred embodiment and the appended claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a partial isometric view of the preferred embodiment completely removed from the hypodermic syringe.

FIGURE 2 is an elevational view of the preferred embodiment attached to a disposable medical syringe.

FIGURE 3 is an elevational view of the preferred embodiment attached to a commonly used metal dental syringe.

FIGURE 4 is a fragmentary view of the preferred embodiment prior to injection into a patient.

FIGURE 5 is a fragmentary view of the preferred embodiment during injection into a patient.

FIGURE 6 is a fragmentary view of the preferred embodiment after removing the needle from a patient.

FIGURE 7 is a exploded view of the preferred embodiment with the syringe omitted.

FIGURE 8 is a cutaway partial isometric view of the shield depicting the springless unitary embodiment.

FIGURE 9 is a cross sectional view of the preferred embodiment shown in its normal position ready for use.

FIGURE 10 is a cross sectional view of the preferred embodiment shown in its retracted position.

FIGURE 11 is a cross sectional view of the preferred embodiment shown in its expanded position ready for disposal.

FIGURE 12 is a side view of the blood sampling vacuum syringe embodiment.

FIGURE 13 is a fragmentary view of the second embodiment employing a hollow protective cap for protection prior to use.

BEST MODE FOR CARRYING OUT THE INVENTION

The best mode for carrying out the invention is presented in terms of a preferred embodiment for medical and dental syringes, needle assemblies for
5 direct connection to tubing, as well as a blood sampling syringe and an alternate addition of a protective cap.

The preferred embodiment, as shown in FIGURES 1 through 10 is comprised of an automatic guard for a
10 hypodermic syringe that includes a barrel 20, plunger 22, tapered barrel adapter 24, needle hub 26 and a hollow needle 28. The invention modifies the syringe only to the extent that the tapered barrel adapter 24 is configured somewhat different in that it contains a
15 tapered portion 30 for attachment purposes otherwise, the syringe remains as prior art has historically established. FIGURES 9-11 illustrate best the improvement as only the adapter 24 and needle 28 with hub 26 are shown. It should also be noted that the hub
20 26 may be eliminated and the adaptor 24 may also serve as the anchor for the needle 28.

The adaptor 24 may be molded into different configurations to securely attach to syringes of various applications such as a luer taper type for
25 medical syringes and a threaded type for a double sharp tipped needle for dental and blood sampling vacuum syringes.

The disposable needle guard includes a slidable anchor sleeve 32, with an opening 34 in the center,
30 slid over the needle 28. FIGURES 7, 9-11 illustrate this sleeve by itself and in its various operable positions relative to the needle 28, at any rate the sleeve 32 is free to slide along the needle as required by the operative action. For connecting purposes, the
35 sleeve 32 contains an aperture 36 therethrough, shown

best in FIGURE 7, for attachment purposes.

Sleeve position limiting means, in the form of a sleeve lanyard 38, is made using a flexible metallic wire or a synthetic fiber cord, that joins the sleeve 32 and adapter 24 together permitting the sleeve to slide upon the needle 23 only a predetermined distance, in effect, limiting the sleeves travel. The lanyard 38 is free to randomly coil when the sleeve approaches the adapter thereby only limiting travel in one direction.

A needle tip guard 40 is also slid over the needle 28 through a hole 42 penetrating the center of the guard permitting the guard to slide freely to and fro. The guard 40 is shown best in FIGURES 7, 9-11 and contains a radially disposed bore 42 therethrough and an external taper 44 on one end for connecting purposes, described later. Further, the guard 40 contains a recessed groove 46 in the side juxtaposed parallel with the aperture 36 again with its purpose described later.

The end of the guard 40 furthest away from the syringe alternately includes a cap receiving taper 48 to which a hollow protective cap 50 may be added. The cap 50 includes an internal taper for a frictional fit and is well known in the art in that configuration. This alternate embodiment is illustrated in FIGURE 13 and may be added to the invention for convenience in storage prior to use but is obviously unnecessary after use as the needle is no longer exposed.

The guard 40, like the sleeve 32, includes guard travel limiting means in the form of a guard lanyard 52 of the same material and construction as the sleeve lanyard 38. This device is joined to the guard 40 on one end and the barrel adapter 24 on the other permitting the guard to slide upon the needle 28 only a predetermined distance from the adapter 24. FIGURES 7, 9-11 illustrate this function and it is obvious to

combine both lanyards 38 and 52 into one piece with a intermediate stop if so desired. The guard lanyard 52 also freely coils when the guard 40 is manually pushed toward the syringe to expose more of the hollow needle 28 during use. It should also be noted that this travel limiting means may be integrally incorporated in other interconnecting elements of the invention and serve the same purpose.

5
10
15
20
An expanding flexible shield 54 is positioned between, and physically connected to, the barrel adapter 24 and the needle tip guard 40 on the external taper 44. The shield 54 by its expanding nature, forces the guard away from the adapter also the shield, being cylindrical in shape, encloses and protects the sleeve 32 and needle 28 located within. The shield 54 is flexible and slips over tapers on each adjoining end of the adapter 24 and the guard 40 creating an enclosed protective sheath. Furthermore, the guard lanyard 52, while limiting the expansion travel of the shield, permits retention of a slight expansive force to stabilize the relationship and maintain the integrity of the enclosure.

25
30
35
The shield 54 is in the form of a corrugated accordion like bellows 58 having a compression spring 56 located tightly inside with the corrugations spaced evenly apart permitting compression in a uniform and orderly manner without appreciably changing diameters when compressed together. The spring 56 is either a metallic or thermoplastic material wound helically pushing the bellows apart and providing an expansive force when pressed together. The spring 56 may be received in an abutment or may be naturally retained by the taper 44. The bellows 58 are formed in corrugations using a synthetic rubber or thermoplastic material molded by heat and pressure or formed by injection molding. Further, in another embodiment, the

spring 56 may be an integral part of the shield 54 in a unitary formulated thermoplastic springless embodiment, shown in FIGURE 8. The shield 54 in this configuration has sufficient resiliency to compress however, it also
5 has the ability to resist this compression in a spring like manner functioning the same as the combination previously described.

A combination latch and needle protecting spring 60 is positioned within the recessed groove 46 of the
10 guard 40 with attaching means in the form of a C-ring 62 pressed over the spring permitting resistive action of the spring on both ends. The spring 60 is illustrated by itself in FIGURE 7 and assembled in
15 FIGURES 9-11 and includes a latching end 64 and a protective end 66. The latching end 64 is releasably connected to the sleeve 32 as illustrated in FIGURES 9-11. The sleeve 32 contains a cylindrical projection 68 on the end opposite the guard 40, best shown in
20 FIGURE 7, and the spring 60 has a projection receiving hole 70 in the latching end 64. The projection 68 on the sleeve 32 enters the hole 70 when the shield 54 is expanded away from the tension of the sleeve lanyard 38 and is therefore unlatched when the shield 54 is manually compressed.

25 The protective end 66 of the spring 60 touches the needle 28 under spring tension and rests there during initial storage and operation as illustrated in FIGURES 9 and 10 as the guard 40 is held away from the adapter 24 limited by the sleeve lanyard 38 while yet under
30 expansive tension of the shield 54.

In use, the guard 40 is manually pulled toward the adapter 24 to expose more needle and to initiate the automatic operation. The latching end 64 of the spring 60 disengages the projection 68 from the hole 70 by the
35 spring action that physically moves the latching end 64 away from the sleeve 32, as shown sequentially in

FIGURES 9 and 10. With the latch disengaged, the guard 40 has a tendency to move away from the syringe however, the needle 28 is then inserted into the patient as shown in FIGURES 4-6 and the guard then touches the patient's skin. This same unlatching may take place automatically when the needle 28 is inserted into the patient and the guard 40 is forced against the skin as shown pictorially in FIGURE 5 and FIGURE 10.

In either event, once the spring 60 is unlatched and upon withdrawal of the needle from the patient, the guard 40 is slid along the needle 28 under the urging of the shield compression spring 56 until the travel limiting guard lanyard 52 reaches its full extension. Either slightly prior to or simultaneously with this full extension, the protective end 66 of the spring 60 slips over the end of the needle 28 under spring tension fully protecting the sharp end with a mechanical barrier. This final functional operation is illustrated in FIGURES 6 and 11 and permanently protects and retains the needle within the tip guard 40 and shield 54 for safe disposal. It will be noted that once the shield 54 is fully extended and the protective end 66 of the spring 60 has covered the needle point, there is no way of reversing the procedure, therefore, the syringe is rendered safe and foolproof and may be handled without danger as any blood remaining on or in the end of the needle is fully enclosed and protected from contaminating the medical practitioner using the syringe or other's handling the disposal.

Another application for the automatic disposable needle guard is adapted to a vacuum tube blood sampling syringe as illustrated in FIGURE 12. While the syringe is somewhat different and the plunger 22 becomes the vacuum tube, the invention is identical in form, fit and function however, in use particularly, when drawing blood from a vein in the arm, the needle 28 is not

always entirely inserted therefore the guard may be manually retracted to unlatch the spring 60 permitting automatic operation to enclose the needle when the procedure is completed.

5 While the invention has been described in complete detail and pictorially shown in the accompanying drawings it is not to be limited to such details, since many changes and modifications may be made in the invention without departing from the spirit and scope
10 thereof. Hence, it is described to cover any and all modifications and forms which may come within the language and scope of the claims.

CLAIMS

1. An automatic disposable needle guard for a hypodermic system that includes an adapter, a needle hub and a hollow needle, the disposable needle guard comprising:

- a) a slidable anchor sleeve having an opening in the center thereof with the sleeve disposed over the hollow needle through the opening such that the sleeve slides freely thereupon,
- b) sleeve position limiting means joined to the sleeve permitting the sleeve to slide upon the needle only a predetermined distance from the syringe adapter,
- c) a needle tip guard having a hole therein with the guard disposed over the hollow needle through the hole permitting the guard to slide freely thereupon,
- d) guard travel limiting means joined to the guard permitting the guard to slide upon the needle only a predetermined distance from the syringe adapter,
- e) an expanding flexible shield having a first end and a second end, disposed between the adapter and guard with the first end gripping the adapter and the second end gripping the guard urging the guard away from the adapter also protecting the needle and sleeve positioned thereunder, and

5 f) a combination latch and needle protecting
spring joined to said guard with
attaching means said spring having a
latching end and a protection end with
the latching end releasably connected to
the sleeve and the protecting end
resiliently contiguous with the hollow
needle with the shield urging the guard
away from the adapter held only by sleeve
10 positioning limiting means and in use
when the guard is pulled toward the
adapter the spring is disengaged from the
sleeve and the guard permitting
retraction of the sleeve and the guard
over the needle until the sleeve touches
the hub, further upon withdrawal of the
needle from a patient the guard is slid
15 along the needle under the urging of the
shield until the guard travel limiting
means reaches full extension and the
protecting end of the spring releases
tension and slips over the hollow needle
tip protecting and retaining the needle
within the tip guard and shield for safe
20 disposal.

2. The automatic disposable needle guard as
recited in claim 1 further comprising, said sleeve
having an aperture therethrough to retain the sleeve
position limiting means.

30

3. The automatic disposable needle guard as recited in claim 1 wherein said sleeve position limiting means further comprises a flexible metallic wire lanyard having the ability to randomly coil between the hollow needle and the shield.

4. The automatic disposable needle guard as recited in claim 1 wherein said sleeve position limiting means further comprises a synthetic fiber cord lanyard having the ability to randomly coil between the hollow needle and the shield.

5. The automatic disposable needle guard as recited in claim 1 wherein said needle tip guard having a radially disposed bore therein to retain the guard position limiting means.

6. The automatic disposable needle guard as recited in claim 1 wherein said needle tip guard further comprises an external taper of a size to retain said expanding flexible shield for connection and retention thereof.

7. The automatic disposable needle guard as recited in claim 1 wherein said needle tip guard further comprises a first end and a second end with the first end away from the syringe having a cap receiving taper thereon.

8. The automatic disposable needle guard as recited in claim 7 wherein said barrel adapter further comprises a receiving taper for a long cap enclosing the entirety of the needle adapter, hub and needle.

5 9. The automatic disposable needle guard as recited in claim 7 further comprising a hollow protective cap having an internal taper of a size to fit over the guard cap receiving taper for protection of the needle prior to use.

10 10. The automatic disposable needle guard as recited in claim 1 further comprising expanding flexible shield a corrugated accordion like bellows having a compression spring disposed tightly within with the bellows compressing in a uniform manner not changing diameters when pressed together and the spring urging the bellows to expand to the maximum extent.

15 11. The automatic disposable needle guard as recited in claim 10 wherein said compression spring further comprises a metallic material wound in a helical manner.

20 12. The automatic disposable needle guard as recited in claim 10 wherein said compression spring further comprises a thermoplastic material wound in a helical manner.

 13. The automatic disposable needle guard as recited in claim 10 wherein said bellows further comprises a synthetic rubber material molded by heat and pressure.

25 14. The automatic disposable needle guard as recited in claim 10 wherein said bellows further comprises a latex molded material molded by heat and pressure.

15. The automatic disposable needle guard as recited in claim 10 wherein said bellows further comprises a thermoplastic material formed by injection molding.

5 16. The automatic disposable needle guard as recited in claim 1 wherein said expanding flexible shield further comprises a springless, unitary formulated, thermoplastic structure having the integral ability to compress in an accordion like shape without
10 changing diameter and the constant ability to maintain expansive characteristics in a compression spring like manner.

 17. The automatic disposable needle guard as recited in claim 1 wherein said guard travel limiting
15 means further comprises a flexible metallic wire lanyard having the ability to randomly coil between the hollow needle and the shield.

 18. The automatic disposable needle guard as recited in claim 1 wherein said guard travel limiting
20 means further comprises a synthetic fiber cord lanyard having the ability to randomly coil between the hollow needle and the shield.

 19. The automatic disposable needle guard as recited in claim 1 further comprising said slidable
25 anchor sleeve having a cylindrical projection on an end opposite said guard and said spring having a projection receiving hole in the latching end such that the projection enters the hole when the shield is expanded away from the position limiting means and is unlatched
30 when the shield is manually compressed.

20. The automatic disposable needle guard as recited in claim 1 further comprising a C-ring pressed over the spring into guard holding the spring in place permitting resistive action of the spring on both the latching end and the protection end.

21. The automatic disposable needle guard for a vacuum tube blood sampling syringe that includes a barrel, a vacuum tube, a taper barrel adapter, a needle hub and a double sharp tipped hollow needle, the disposable needle guard comprising:

- a) a slidable anchor sleeve having an opening in the center thereof with the sleeve disposed over the needle through the opening such that the sleeve slides freely thereupon,
- b) sleeve position limiting means joined to the sleeve and barrel adapter permitting the sleeve to slide upon the needle only a predetermined distance from the syringe barrel adapter,
- c) a needle tip guard having a hole therein with the guard disposed over the needle through the hole permitting the guard to slide freely thereupon,
- d) guard travel limiting means joined to the guard and barrel adapter permitting the guard to slide upon the needle only a predetermined distance from the syringe barrel adapter,
- e) expanding flexible shield having a first end and a second end, disposed between the barrel adapter and guard with the first end gripping the barrel adapter and the second end gripping the guard urging the guard away from the adapter also

protecting the needle and sleeve positioned thereunder, and

- 5 f) a combination latch and needle protecting spring joined to said guard with attaching means said spring having a latching end and a protection end with the latching end releasably connected to the sleeve and the protecting end resiliently contiguous with the needle
- 10 with the shield urging the guard away from the adapter held only by sleeve positioning limiting means and in use when the guard is pulled toward the adapter the spring is disengaged from the sleeve permitting retraction of the sleeve and the guard over the needle
- 15 until the sleeve touches the hub, further upon withdrawal of the needle from a patient the guard is slid along the needle under the urging of the shield until the guard travel limiting means reaches full extension and the protecting end of the spring releases tension and slips over the needle tip protecting and
- 20 retaining the needle within the tip guard and shield for safe disposal.
- 25

22. An automatic disposable needle guard for a hypodermic syringe that includes a barrel, a plunger, a tapered barrel adapter, a needle hub and a hollow needle, the disposable needle guard comprising:

- 5 a) a slidable anchor sleeve having an opening in the center thereof with the sleeve disposed over the syringe needle through the opening such that the sleeve slides freely thereupon,
- 10 b) sleeve position limiting means joined to the sleeve and barrel adapter permitting the sleeve to slide upon the needle only a predetermined distance from the syringe barrel adapter,
- 15 c) a needle tip guard having a hole therein with the guard disposed over the needle through the hole permitting the guard to slide freely thereupon,
- 20 d) guard travel limiting means joined to the guard and barrel adapter permitting the guard to slide upon the needle only a predetermined distance from the syringe barrel adapter,
- 25 e) an expanding flexible shield having a first end and a second end, disposed between the barrel adapter and guard with the first end gripping the barrel adapter and the second end gripping the guard urging the guard away from the adapter
- 30 also protecting the needle and sleeve positioned thereunder, and

5 f) a combination latch and needle protecting
spring joined to said guard with
attaching means said spring having a
latching end and a protection end with
the latching end releasably connected to
the sleeve and the protecting end
resiliently contiguous with the syringe
needle with the shield urging the guard
away from the adapter held only by sleeve
positioning limiting means and in use
when the guard is pulled toward the
adapter the spring is disengaged from the
sleeve permitting retraction of the
sleeve and the guard over the needle
until the sleeve and guard touch the hub,
further upon withdrawal of the needle
from a patient the guard is slid along
the needle under the urging of the shield
until the guard travel limiting means
reaches full extension and the protecting
end of the spring releases tension and
slips over the hollow needle tip of the
syringe protecting and retaining the
needle within the tip guard and shield
for safe disposal.

23. The automatic disposable needle guard as
recited in claim 22 further comprising, said sleeve
having an aperture therethrough to retain the sleeve
position limiting means.

24. The automatic disposable needle guard as recited in claim 22 wherein said sleeve position limiting means further comprises a flexible metallic wire lanyard having the ability to randomly coil
5 between the hollow needle and the shield.

25. The automatic disposable needle guard as recited in claim 22 wherein said sleeve position limiting means further comprises a synthetic fiber cord lanyard having the ability to randomly coil between the
10 hollow needle and the shield.

26. The automatic disposable needle guard as recited in claim 22 wherein said needle tip guard having a radially disposed bore therein to retain the guard position limiting means.

15 27. The automatic disposable needle guard as recited in claim 22 wherein said needle tip guard further comprises an external taper of a size to retain said expanding flexible shield for connection and retention thereof.

20 28. The automatic disposable needle guard as recited in claim 22 wherein said needle tip guard further comprises a first end and a second end with the first end away from the syringe having a cap receiving taper thereon.

25 29. The automatic disposable needle guard as recited in claim 28 wherein said barrel adapter further comprises a receiving taper for a long cap enclosing the entire needle assembly.

30. The automatic disposable needle guard as recited in claim 28 further comprising a hollow protective cap having an internal taper of a size to fit over the guard cap receiving taper for protection of the needle prior to use.

10 31. The automatic disposable needle guard as recited in claim 22 further comprising an expanding flexible shield and a corrugated accordion like bellows having a compression spring disposed tightly within with the bellows compressing in a uniform manner not changing diameters when pressed together and the spring urging the bellows to expand to the maximum extent.

15 32. The automatic disposable needle guard as recited in claim 31 wherein said compression spring further comprises a metallic material wound in a helical manner.

20 33. The automatic disposable needle guard as recited in claim 31 wherein said compression spring further comprises a thermoplastic material wound in a helical manner.

34. The automatic disposable needle guard as recited in claim 31 wherein said bellows further comprises a synthetic rubber material molded by heat and pressure.

25 35. The automatic disposable needle guard as recited in claim 31 wherein said bellows further comprises a latex molded material molded by heat and pressure.

36. The automatic disposable needle guard as recited in claim 31 wherein said bellows further comprises a thermoplastic material formed by injection molding.

5 37. The automatic disposable needle guard as recited in claim 22 wherein said expanding flexible shield further comprises a springless, unitary formulated, thermoplastic structure having the integral ability to compress in an accordion like shape without
10 changing diameter and the constant ability to maintain expansive characteristics in a compression spring like manner.

 38. The automatic disposable needle guard as recited in claim 22 wherein said guard travel limiting
15 means further comprises a flexible metallic wire lanyard having the ability to randomly coil between the hollow needle and the shield.

 39. The automatic disposable needle guard as recited in claim 22 wherein said guard travel limiting
20 means further comprises a synthetic fiber cord lanyard having the ability to randomly coil between the hollow needle and the shield.

 40. The automatic disposable needle guard as recited in claim 22 further comprising said slidable
25 anchor sleeve having a cylindrical projection on an end opposite said guard and said spring having a projection receiving hole in the latching end such that the projection enters the hole when the shield is expanded away from the position limiting means and is unlatched
30 when the shield is manually compressed.

41. The automatic disposable needle guard as recited in claim 22 further comprising a C-ring pressed over the spring into guard holding the spring in place permitting resistive action of the spring on both the
5 latching end and the protection end.

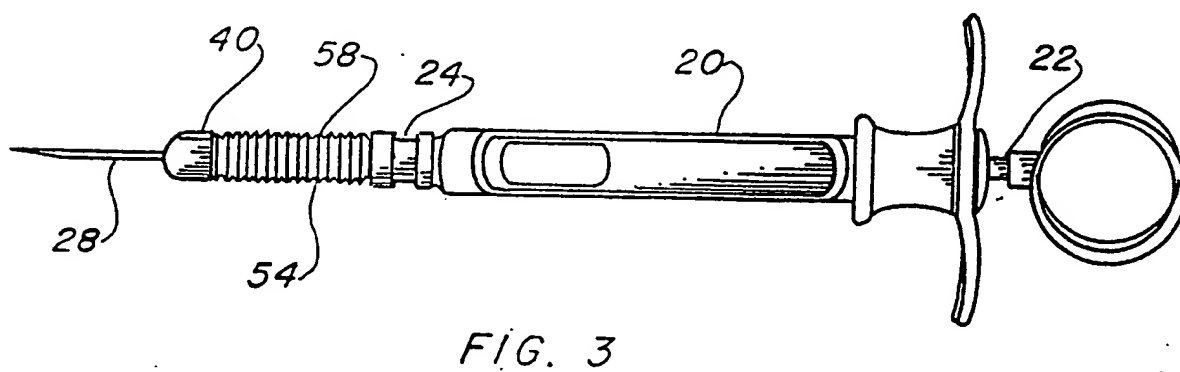
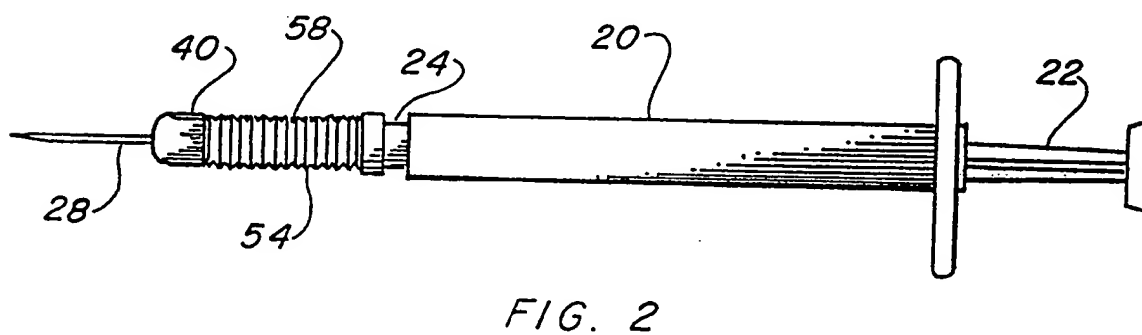
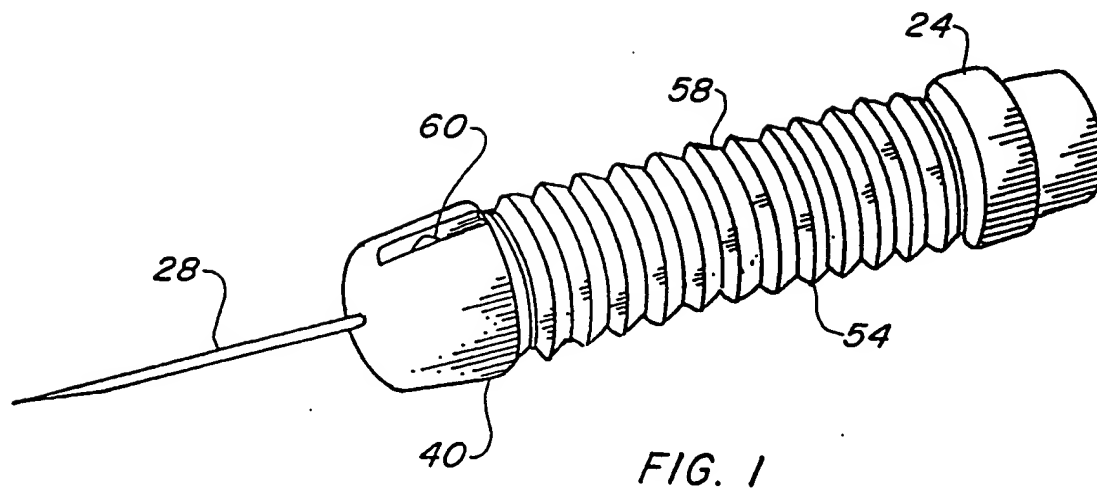
AMENDED CLAIMS

[received by the International Bureau on 17 December 1992 (17.12.92);
new claim 42 added;
other claims unchanged (1 page)]

42. A mounting member adapted for association with a hollow needle comprising:

- 5 a) a needle cover member spaced from said mounting member and having a central aperture therethrough to allow the passage of said needle therethrough, said needle cover member being slidably biased away from said mounting member and being slidably and releasably retained on said needle and latched by means of a latch member operatively secured to said mounting member in a needle exposed position;
- 10 b) said latch member being disengaged when said needle cover member is urged towards said mounting member and being adapted to slide forwardly of said needle terminus into a needle protecting position when said needle cover member is unlatched from said mounting member.

1/3



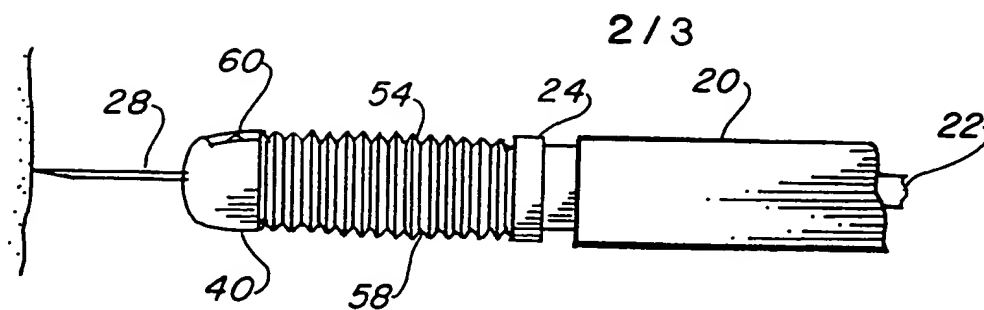


FIG. 4

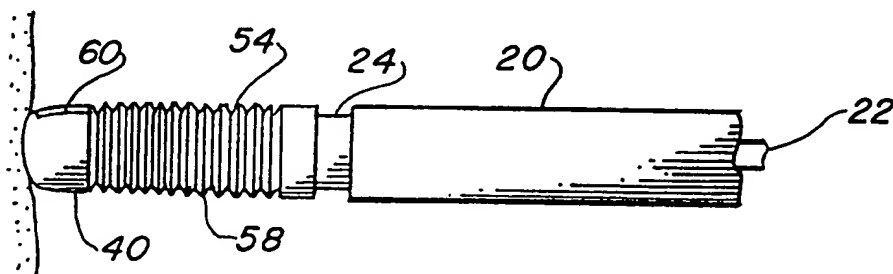


FIG. 5

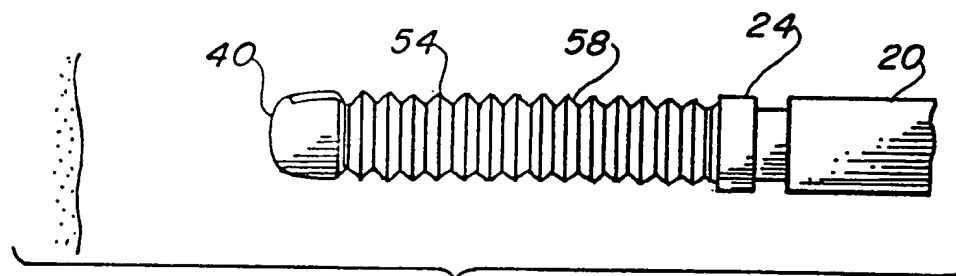


FIG. 6

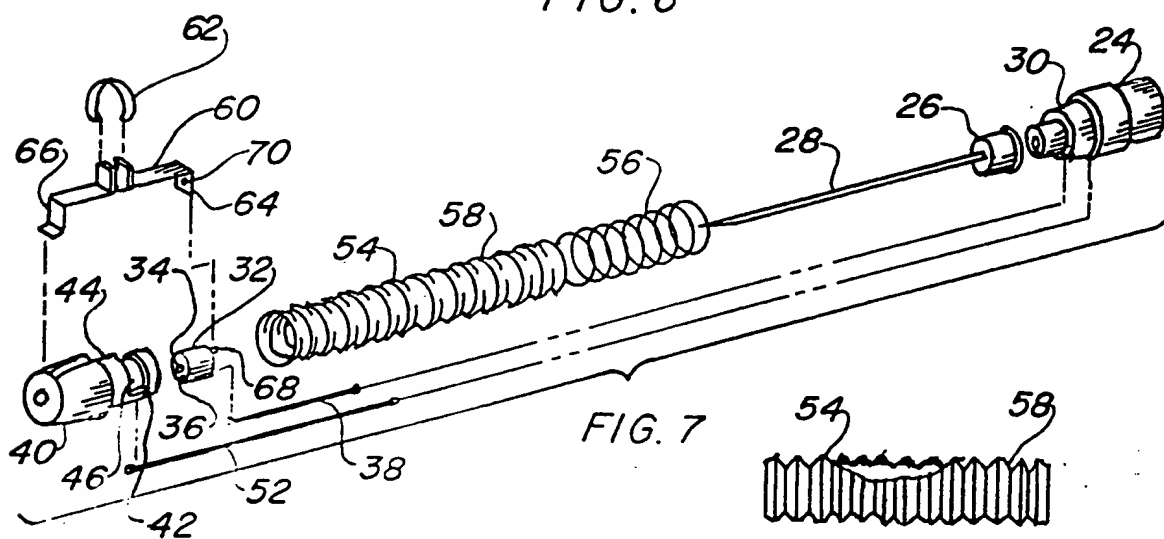


FIG. 7

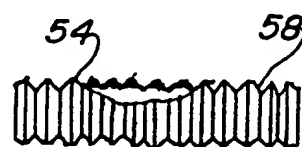
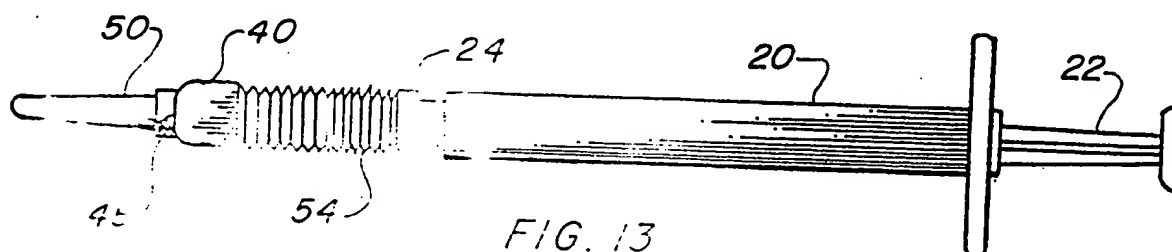
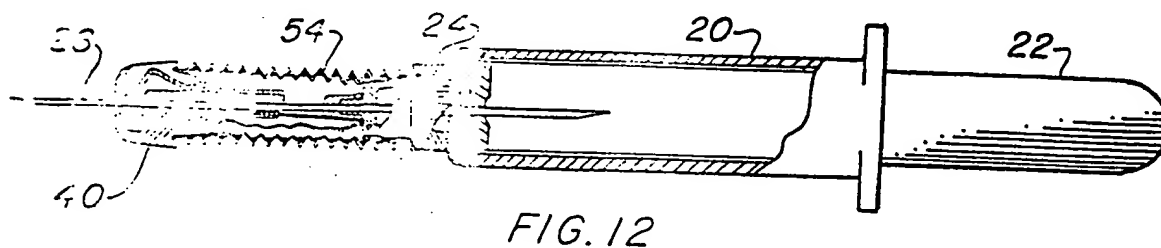
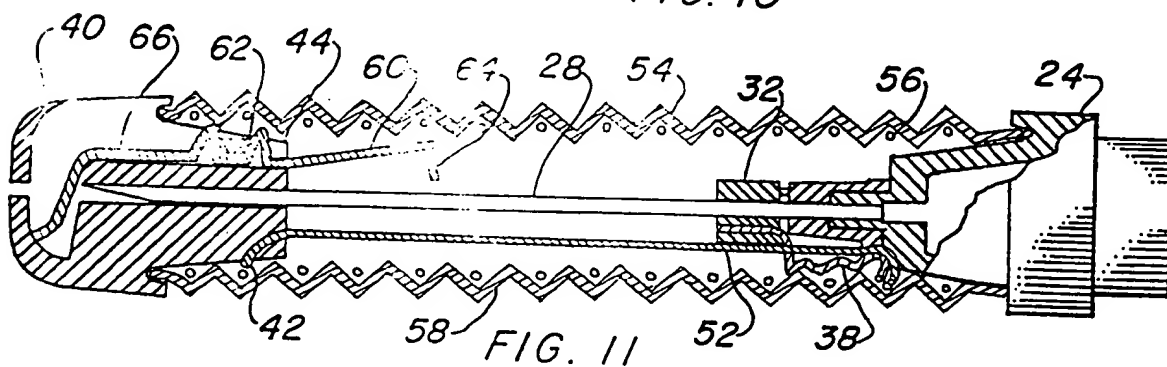
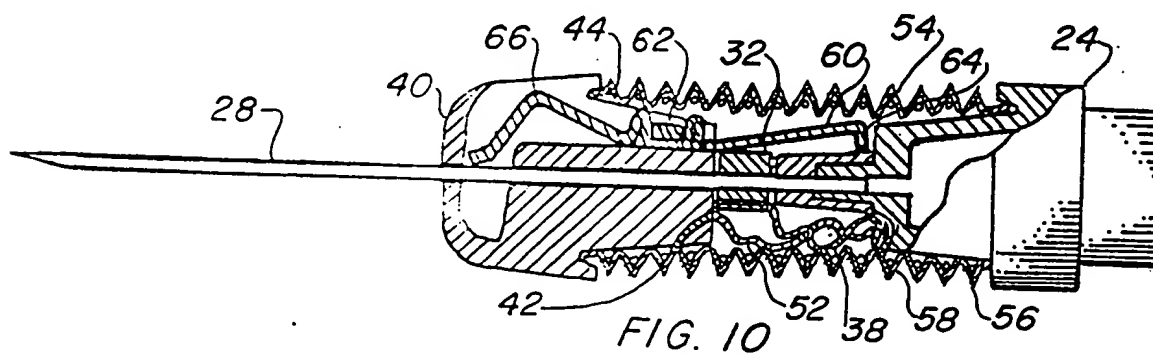
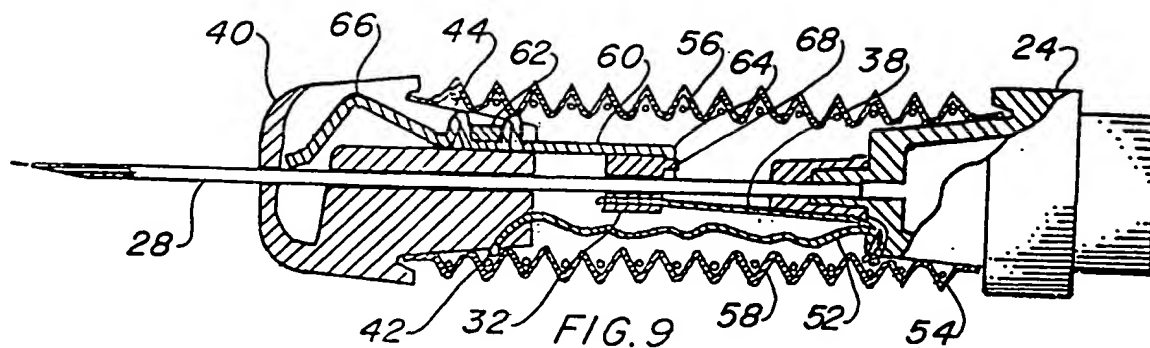


FIG. 8

3/3



SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US92/05280

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61M 5/32,5/00

US CL : 604/198,263

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/110,192,197,199

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,104,384 (PARRY) 14 April 1992, See figures 2 and 3.	1-41
A	US, A, 4,813,940 (PARRY) 21 March 1989, See entire document.	1-41
A	US, A, 4,892,521 (LAICO ET AL.) 09 January 1990, retaining element (48).	1-41
A	US, A, 3,808,688 (HAGEN) 19 January 1989, See entire reference.	1-41
A	US, A, WO 91/13643 (GUERINIEAU) 19 September 1991, See figures 4-6.	1-41
A	US, A, 4,795,432 (KARCZMER) 03 January 1989, See entire reference, especially figure 2.	1-41
A	US, A, 4,887,998 (MARTIN ET AL.) 19 December 1989, See entire document, especially figures 2-5.	1-41

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date(s)		

Date of the international search

23 SEPTEMBER 1992

Date of mailing of the international search report

09 NOV 1992

Name and mailing address of the ISA/
Commission of Patents and Trademarks
Box PCT
Washington, D.C. 20531

Authorized officer

CHALIN SMITH

Facsimile No. NOT APPLICABLE

Telephone No. (703) 308-0858

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US92/05280

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US. A, 5,015,242 (HEIFETZ) 14 May 1991, See entire document.	1-41
A	US. A, 4,978,344 (DOMBROWSKI ET AL.) 18 December 1990, See entire document.	1-41